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<b>TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371</b>		ATTORNEY'S DOCKET NUMBER 029869.00004-US01
INTERNATIONAL APPLICATION NO. PCT/US03/20960		U.S. APPLICATION NO. (if known, see 37 CFR 1.5) 10/519,804
INTERNATIONAL FILING DATE 1 July 2003		PRIORITY DATE CLAIMED 1 July 2002
TITLE OF INVENTION NOVEL COMPOUNDS, PHARMACEUTICAL COMPOSITIONS CONTAINING SAME, AND METHODS OF USE FOR SAME		
APPLICANT(S) FOR DO/EO/US Francis P. Kuhajda et al.		
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:		
1. <input type="checkbox"/> This is a <b>FIRST</b> submission of items concerning a submission under 35 U.S.C. 371.		
2. <input checked="" type="checkbox"/> This is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a submission under 35 U.S.C. 371.		
3. <input type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.		
4. <input type="checkbox"/> The US has been elected (Article 31).		
5. <input type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371 (c)(2))		
a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau).		
b. <input type="checkbox"/> has been communicated by the International Bureau.		
c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).		
6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).		
a. <input type="checkbox"/> is attached hereto.		
b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4).		
7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))		
a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau).		
b. <input type="checkbox"/> have been communicated by the International Bureau.		
c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.		
d. <input type="checkbox"/> have not been made and will not be made.		
8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).		
9. <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).		
10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).		
<b>Items 11 to 20 below concern document(s) or information included:</b>		
11. <input checked="" type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.		
12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.		
13. <input type="checkbox"/> A preliminary amendment.		
14. <input type="checkbox"/> An Application Data Sheet under 37 CFR 1.76.		
15. <input type="checkbox"/> A substitute specification.		
16. <input checked="" type="checkbox"/> A power of attorney and/or change of address letter.		
17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 – 1.825.		
18. <input type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4).		
19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).		

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U.S. APPLICATION NO. (if known, see 37 CFR 1.5) <b>10/519,804</b>		INTERNATIONAL APPLICATION NO. <b>PCT/US03/20960</b>		ATTORNEY'S DOCKET NUMBER <b>029869.00004-US01</b>	
20. <input checked="" type="checkbox"/> Other items or information: Petition for Extension of Time under 37 CFR 1.136(a) (in duplicate); Statements under 37 CFR 3.73(b) with copies of the assignments (one executed on behalf of Johns Hopkins University and one executed on behalf of FASgen, LLC); Verified Statement (Declaration) Claiming Small Entity Status (37 C.F.R. § 1.27--Small Business Concern) executed on behalf of FASgen, LLC; Verified Statement (Declaration) Claiming Small Entity Status (37 C.F.R. §§ 1.9(e) and 1.27(d))--Nonprofit Organization executed on behalf of Johns Hopkins University					
The following fees have been submitted				<b>CALCULATIONS</b>	<b>PTO USE ONLY</b>
21. <input type="checkbox"/> Basic national fee (37 CFR 1.492(a)) ..... \$300				\$	
22. <input type="checkbox"/> Examination fee (37 CFR 1.492(c)) If the written opinion of the ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) ..... \$0 All other situations ..... \$200				\$	
23. <input type="checkbox"/> Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) ..... \$0 Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority ..... \$100 International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB ..... \$400 All other situations ..... \$500				\$	
<b>TOTAL OF 21, 22 and 23 =</b>				\$ 0.00	
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.					
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE		
- 100 =	/50 =		x \$250.00	\$	
Surcharge of \$130 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).				\$	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	- 20 =		x		
Independent claims	- 3 =		x		
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+		
<b>TOTAL OF ABOVE CALCULATIONS =</b>				\$ 0.00	
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.				0.00	
<b>SUBTOTAL =</b>				\$ 0.00	
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).				\$	
<b>TOTAL NATIONAL FEE =</b>				\$ 0.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +				\$	
Extension for response within fifth month (37 CFR 1.17(a)(5))				\$ 1,080.00	
<b>TOTAL FEES ENCLOSED =</b>				\$ 1080.00	
				Amount to be refunded:	\$
				Amount to be charged	\$

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

- a. ☒ A check in the amount of \$ 1080.00 to cover the above fees is enclosed.
- b. ☐ Please charge my Deposit Account No. \_\_\_\_\_ in the amount of \$ \_\_\_\_\_ to cover the above fees.  
A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-0740. A duplicate copy of this sheet is enclosed.
- d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038

**NOTE:** Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

  
SIGNATURE

N. Whitney Wilson  
NAME

CUSTOMER NUMBER: 26853

38,661  
REGISTRATION NUMBER

Docket No.: 029869.00004-US01  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Francis P. Kuhajda et al.

Application No.: 10/519,804 ✓

Group Art Unit: Not Yet Assigned

Filed: December 29, 2004

Examiner: Not Yet Assigned

For: NOVEL COMPOUNDS, PHARMACEUTICAL  
COMPOSITIONS CONTAINING SAME, AND  
METHODS OF USE FOR SAME

**TRANSMITTAL LETTER**

MS PCT

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Enclosed are the following items for filing in connection with the above-referenced  
Patent Application:

1. Petition for Extension of Time under 37 CFR 1.136(a) (in duplicate);
2. Transmittal Letter to the United States Designated/Elected Office (DO/EO/US)  
Concerning a Submission under 35 U.S.C. 371 (in duplicate)
3. Copy of the Notification of Missing Requirements under 35 U.S.C. 371 in the  
United States Designated/Elected Office (DO/EO/US);
4. Declaration for Utility Patent Application;
5. Verified Statement (Declaration) Claiming Small Entity Status (37 C.F.R. § 1.27  
-- Small Business Concern) executed on behalf of FASgen, LLC;

6. Verified Statement (Declaration) Claiming Small Entity Status (37 C.F.R. §§ 1.9(e) and 1.27(d)) -- Nonprofit Organization executed on behalf of Johns Hopkins University;
7. Power of Attorney and Correspondence Address Indication Form executed on behalf of FASgen, LLC;
8. Power of Attorney and Correspondence Address Indication Form executed on behalf of Johns Hopkins University;
9. Statement under 37 CFR 3.73(b) executed on behalf of FASgen, LLC with a copy of the assignment;
10. Statement under 37 CFR 3.73(b) executed on behalf of Johns Hopkins University with copies of the assignments;
11. Information Disclosures Statement;
12. Form PTO/SB/08a/b;
13. Twenty-one cited documents;
14. Check No. 362788 to cover the five-months extension of time fee; and
15. Return receipt postcard.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 50-0740, under Docket No. 029869.00004-US01. A duplicate copy of this paper is enclosed.

It is not believed that extensions of time or fees for net addition of claims are required beyond those that may otherwise be provided for in documents accompanying this paper. However, if additional extensions of time are necessary to prevent abandonment of this

application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor (including fees for net addition of claims) are hereby authorized to be charged to our Deposit Account No. 50-0740.

Dated: May 19, 2006

Respectfully submitted,

By 

N. Whitney Wilson

Registration No.: 38,661

COVINGTON & BURLING

1201 Pennsylvania Avenue, N.W.

Washington, DC 20004-2401

(202) 662-6000

Attorney for Applicant



## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
 United States Patent and Trademark Office  
 Address: COMMISSIONER FOR PATENTS  
 P.O. Box 1450  
 Alexandria, Virginia 22313-1450  
 www.uspto.gov

U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
10/519,804	Francis P Kuhadja	#10001.\$190

26853  
 COVINGTON & BURLING  
 ATTN: PATENT DOCKETING  
 1201 PENNSYLVANIA AVENUE, N.W.  
 WASHINGTON, DC 20004-2401

INTERNATIONAL APPLICATION NO.	
PCT/US03/20960	
I.A. FILING DATE	PRIORITY DATE
07/01/2003	07/01/2002

CONFIRMATION NO. 7358

## 371 FORMALITIES LETTER



\*OC000000017285537\*

Date Mailed: 10/21/2005

### NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Copy of the International Application filed on 12/29/2004
- Copy of the International Search Report filed on 12/29/2004
- Small Entity Statement filed on 12/29/2004
- Copy of references cited in ISR filed on 12/29/2004
- U.S. Basic National Fees filed on 12/29/2004
- Priority Documents filed on 12/29/2004

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.

## SUMMARY OF FEES DUE:

Total additional fees required for this application is \$-250 for a Large Entity:

(A previous payment of \$250 will be applied to the additional fees indicated above.)

**ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.**

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

*A copy of this notice **MUST** be returned with the response.*

DEBORAH D WILLIAMS

Telephone: (703) 308-9140 EXT 205

PART 1 - ATTORNEY/APPLICANT COPY

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/519,804	PCT/US03/20960	#10001.\$190

FORM PCT/DO/EO/905 (371 Formalities Notice)